K063158

510(k) Summary

11-14-06

Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Susan Lewandowski Manager, Spine Regulatory Affairs Telephone: 610-719-5712 Facsimile: 610-719-5102 Email: lewandowski.susan@synthes.com
Date Prepared:	November 2006
Trade Name:	Synthes Antegra System
Common Name:	Lumbosacral Plate Fixation System
Classification:	21 CFR 888.3060 – Spinal Intervertebral Body Fixation Orthosis Class II Orthopaedic and Rehabilitation Devices Panel Product Code KWQ
Predicate Device:	Synthes Anterior Tension Band (ATB) System – K022791
Device Description:	The Synthes Antegra System consists of lumbar and sacral plates (one-level and two-level) and cancellous screws with locking heads. The plate attaches to the anterior portion of the lumbar and lumbosacral spine (L1-S1). The screw heads and screw holes in the plates have matching conical profiles and are threaded. The screw head locks to the plate and is nominally flush with the plate surface when properly seated. The screws have a dual-core design. The plates and screws are manufactured from Titanium Aluminum Niobium (Ti-6Al-7Nb) ASTM F1295, the same as the predicate device.
Intended Use / Indications for Use:	Synthes Antegra System is intended for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels. Synthes Antegra System is indicated in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of the

	following: Fracture (including dislocation and subluxation), Tumor, Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), Pseudoarthrosis, Spondylolysis, Spondylolisthesis, Scoliosis, Lordotic deformities of the spine, Spinal stenosis, and Failed previous spine surgery. Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
Comparison of the technological characteristics of the device to the predicate device:	The Synthes Antegra System is a result of design modifications to the predicate device. It is substantially equivalent to the predicate in design, function, material and intended use.
Performance Data (Nonclinical and/or Clinical)	*Non-Clinical Performance and Conclusions:* Bench testing results demonstrate that the Synthes Antegra System is substantially equivalent to the predicate device. *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Synthes Spine
% Ms. Susan Lewandowski
Manager, Spine Regulatory Affairs
1302 Wrights Lane East
West Chester, Pennsylvania 19380

NOV 1 4 2006

Re: K063158
Trade/Device Name: ANTEGRA System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: ClassII
Product Code: KWQ
Dated: October 16, 2006
Received: October 17, 2006

Dear Mrs. Lewandowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276- 0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Special 510(k) Device Modification

Indications for Use Statement

510(k) Number:

Device Name: Synthes Antegra System [modification to Synthes Anterior Tension Band (ATB) System]

Indications: Synthes Antegra System is intended for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels.

Synthes Antegra System is indicated in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of the following:

- Fracture (including dislocation and subluxation)
- Tumor
- Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Pseudoarthrosis
- Spondylolysis
- Spondylolisthesis
- Scoliosis
- Lordotic deformities of the spine
- Spinal stenosis
- Failed previous spine surgery.

Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use **X** (21 CFR 801 Subpart D)	AND / OR	Over-the-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063158